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Frank C. Eisenschenk

Frank C. Eisenschenk, Ph.D., Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. GEN-100D1
Patent No. 7,105,651

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Lydie Bougueleret, Ilya Chumakov
Issued : September 12, 2006
Patent No. : 7,105,651
For : Nucleic Acids and Vectors Encoding Human Defensin Polypeptide and Applications Thereof

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate
MAR 14 2007
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 C.F.R. § 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:

Column 12, line 22:

“EDNA”

Application Reads:

Page 17, line 33:

--cDNA--

MAR 14 2007

Column 17, line 33:

“specific allele »))”

Column 41, line 26:

“ofa”

Column 41, line 34:

“ofa”

Column 42, line 45:

“form”

Column 44, line 10:

“consisting or”

Column 44, line 14:

“6”

Page 24, line 24:

--specific allele »)--

Amendment dated October 6, 2005,
Original claim 53, renumbered as claim 1:

--of a--

Amendment dated October 6, 2005,
Original claim 54, renumbered as claim 2:

--of a--

Amendment dated January 10, 2005,
Original claim 71, renumbered as claim 12:

--from--

Amendment dated January 10, 2005,
Original claim 95, renumbered as claim 24:

--consisting of--

Examiner's Amendment dated May 3, 2006,
Page 3, original claim 95:

--3--.

A true and correct copy of pages 17 and 24 of the specification as filed and a true and correct copy of Applicants' Amendments dated January 10, 2005 and October 6, 2005 and a true and copy of the Examiner's amendment dated May 3, 2006, which support Applicants' assertion of the errors on the part of the Patent Office accompanies this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

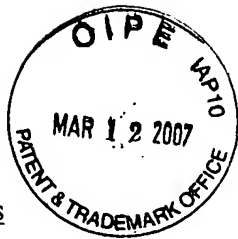
Address: P.O. Box 142950

Gainesville, FL 32614-2950

FCE/gyl/sl

Attachments: Copy of pages 17 and 24 of the specification
Copy of Amendments dated January 10, 2005 and October 6, 2005
Copy of Examiner's Amendment dated May 3, 2006

MAR 14 2007

Legend to the figuresFigure 1

Genomic sequence of hDef-X.

Presented is the entire genomic DNA sequence of hDef-X which exhibits significant
5 homology with the gene encoding hDef-4 (HNP-4).

The sequence has the following sites, the presence of which is deduced by
homology with the hDef-4 sequence:

- CAAT box 1711-1714
- TATA box 1758-1767
- 10 • mRNA start 1836
- exon 1 1836-1874
- splicing site 1 GTCAGT
- Alu insertion 2155-2335
- L1 fragment insertion 2710-2780
- 15 • splicing site 2 CAG
- exon 2 3394-3577
- start of coding phase 3406
- splicing site 3 GTGAGA
- splicing site 4 CAG
- 20 • exon 3 4164-4379
- end of coding phase 4276
- polyadenylation site 4374-4379.

Figure 2

Alignment of the genomic sequences of the human defensins Def-X and Def-4
25 (HNP-4).

Alignment of the entire genomic DNA sequence of the novel defensin Def-X
exhibiting homology with the genomic DNA of hDef-4 (GenBank accession number
U18745).

The annotations present the positions on the hDef-4 sequence of the signals CAAT
30 box, TATA box, splicing sites, beginning and ends of introns/exons, start of
transcription and polyadenylation site.

Figure 3

Alignment of the cDNA sequences of hDef-4 (HNP-4) and hDef-X.

The sequences exhibit an overall homology of 61.4%. The alignment reveals an
35 insert of about 75 bases downstream of a STOP codon, which are present on the
sequence of hDef-4, but not on that of hDef-X; the strong homology continues on
the whole region between the end of this insert and that of the cDNA. Outside this

are compared with the sequences obtained in control subjects, related or not related. A statistical analysis (lod score calculation) makes it possible to conclude as to the significance of the presence of a site of heterozygosity and to its association with a predisposition to cancers.

5

Example 4: Search for point mutations

The point mutations identified as indicated above can then be detected in patients having a potential deficiency in the gene encoding hDef-X, according to numerous methods known to persons skilled in the art. Among these, the following nonexhaustive lists may be mentioned:

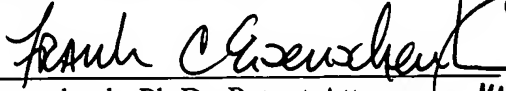
10

- sequencing
- « single nucleotide primer extension » (Syvanen et al., 1990)
- RFLP
- search for « single strand conformation polymorphism »
- 15 • methods based on a cleavage of the mismatched regions (enzymatic cleavage with S1 nuclease, chemical cleavage with various compounds such as piperidine or osmium tetroxide)
- detection of heteroduplex in electrophoresis
- methods based on the use of « allele specific oligonucleotide » (ASO. Stoneking et al., 1991)
- 20 • OLA method (« dual color oligonucleotide ligation assay, Samiotaki et al., 1994)
- ARMS (« amplification refractory mutation system »), or ASA (« allele specific amplification »), or PASA (« PCR amplification of specific allele ») (Wu et al., 25 1989), method.

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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on October 6, 2005.

AMENDMENT UNDER 37 C.F.R. § 1.111
Examining Group 1644
Patent Application
Docket No. GEN-100D1
Serial No. 10/045,180


Frank C. Eisenschenk, Ph.D., Patent Attorney



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : F. Pierre VanderVegt, Ph.D.
Art Unit : 1644
Applicants : Lydie Bougueleret, Ilya Chumakov
Serial No. : 10/045,180
Filed : October 18, 2001
Conf. No. : 4857
For : Nucleic Acids and Vectors Encoding Human Defensin Polypeptide and Applications Thereof

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

AMENDMENT UNDER 37 C.F.R. § 1.111

Sir:

A Petition and Fee for a two-month Extension of Time through and including October 6, 2005, accompanies this Amendment.

In response to the Office Action dated May 6, 2005, please amend the above-identified patent application as follows:

MAR 14 2007

In the Claims

1-52 (canceled).

53. (currently amended). An isolated polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 3; or
- b) a polypeptide ~~comprising~~ consisting of a fragment ~~of~~ of SEQ ID NO: 3 comprising at least 10 consecutive amino acids of SEQ ID NO: 3; wherein said ~~isolated polynucleotide encodes a polypeptide that~~ fragment has at least one biological activity selected from the group consisting of antimicrobial activity or cytotoxic activity ~~recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity~~ [[,]] and ~~cytotoxic activity~~.

54 (currently amended). The isolated polynucleotide according to claim 53, wherein said polynucleotide encodes a polypeptide consisting of a fragment of SEQ ID NO: 3 comprising at least 15 consecutive amino acids of the polypeptide of SEQ ID NO: 3.

55 (previously presented). The isolated polynucleotide according to claim 53, wherein said polynucleotide encodes a polypeptide comprising the sequence of SEQ ID NO: 3.

56 (currently amended). The isolated polynucleotide according to claim 53, wherein said polynucleotide encodes a polypeptide ~~comprising~~ consisting of a fragment ~~fragment of SEQ ID NO: 3~~ of comprising at least 10 consecutive amino acids of the polypeptide of SEQ ID NO: 3.

57 (previously presented). The isolated polynucleotide according to claim 53, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

58 (currently amended). An isolated polynucleotide encoding a polypeptide comprising:

- a) a signal peptide ~~comprising~~ consisting of the sequence of SEQ ID NO: 4;
- b) a proregion ~~comprising~~ consisting of the sequence of SEQ ID NO:5;
- c) a mature peptide ~~comprising~~ consisting of the sequence SEQ ID NO: 6; or
- d) a polypeptide ~~comprising an amino acid~~ consisting of the sequence of SEQ ID

NO: 3 at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or

~~———— e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 6;~~

~~———— wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;~~

~~———— wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 5; and combinations thereof;~~

~~———— wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;~~

~~———— wherein said fragment of SEQ ID NO: 4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;~~

~~———— wherein said fragment of SEQ ID NO:5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5; and combinations thereof; and~~

~~———— wherein said fragment of SEQ ID NO: 6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.~~

59 (currently amended). The isolated polynucleotide according to claim 58, wherein said polynucleotide encodes a polypeptide comprising a signal peptide ~~comprising~~ consisting of the sequence of SEQ ID NO: 4.

60 (currently amended). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a proregion ~~comprising~~ consisting of the sequence of SEQ ID NO: 5.

61 (currently amended). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a mature peptide ~~comprising~~ consisting of the sequence of SEQ ID NO: 6.

62-69 (canceled).

70 (canceled).

71 (currently amended). An isolated polynucleotide encoding a polypeptide selected from the group consisting of:

a) a polypeptide comprising the sequence of SEQ ID NO: 6; and

b) ~~a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and~~

~~—————~~ e) b) a polypeptide ~~comprising~~ consisting of a fragment of ~~comprising~~ at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6; wherein said ~~isolated polynucleotide encodes a polypeptide that~~ fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity ~~the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity~~ [[,]] and cytotoxic activity.

72 (previously presented). The isolated polynucleotide according to claim 71, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

73 (previously presented). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide comprising the sequence of SEQ ID NO: 6.

74 (canceled).

75 (currently amended). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide ~~comprising~~ consisting of a fragment ~~of comprising~~ at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6.

76 (currently amended). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide ~~comprising~~ consisting of a fragment comprising at least 15 consecutive amino acids of the sequence of SEQ ID NO: 6.

77 (currently amended). A vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

a) a polypeptide comprising the sequence of SEQ ID NO: 3; and

~~b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 3; and~~

~~_____ e) b) a polypeptide comprising~~ consisting of a fragment ~~of comprising~~ at least 10 consecutive amino acids of SEQ ID NO: 3; wherein said ~~polynucleotide encodes a polypeptide that~~ fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity ~~the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity and cytotoxic activity.~~

78 (previously presented). The vector according to claim 77, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

79 (previously presented). The vector according to claim 77, further comprising elements ensuring the expression of said polynucleotide in a host cell.

80 (currently amended). A vector comprising a polynucleotide encoding a polypeptide comprising:

- a) a signal peptide ~~comprising~~ consisting of the sequence of SEQ ID NO: 4;
- b) a proregion ~~comprising~~ consisting of the sequence of SEQ ID NO:5;
- c) a mature peptide ~~comprising~~ consisting of the sequence SEQ ID NO: 6; or
- d) a polypeptide ~~comprising~~ consisting of the ~~an amino acid sequence of~~ SEQ ID NO: 3 ~~at least 90% identical over the full length to the amino acid sequence of~~ SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or
- ~~———— e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6;~~
- ~~———— wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;~~
- ~~———— wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 5; and combinations thereof;~~
- ~~———— wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;~~
- ~~———— wherein said fragment of SEQ ID NO: 4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;~~
- ~~———— wherein said fragment of SEQ ID NO:5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the~~

~~active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5; and combinations thereof; and~~
~~wherein said fragment of SEQ ID NO: 6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.~~

81 (previously presented). The vector according to claim 80, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

82 (previously presented). The vector according to claim 80, further comprising elements ensuring the expression of said polynucleotide in a host cell.

83 (currently amended). A vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 6; and
- ~~b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and~~
- ~~c) b) a polypeptide comprising consisting of a fragment of SEQ ID NO: 6 comprising~~
~~of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6; wherein said polynucleotide encodes a polypeptide that~~ fragment ~~has at least one biological activity selected from antimicrobial activity or cytotoxic activity~~
~~the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity and cytotoxic activity.~~

84 (previously presented). The vector according to claim 83, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

85 (previously presented). The vector according to claim 83, further comprising elements ensuring the expression of said polynucleotide in a host cell.

86 (currently amended). A host cell transformed with a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 3; and
- ~~b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 3; and~~
- ~~————— e) b) a polypeptide comprising consisting of a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 3; wherein said polynucleotide encodes a polypeptide that fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity and cytotoxic activity.~~

87 (previously presented). The host cell according to claim 86, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

88 (previously presented). The host cell according to claim 86, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

89 (currently amended). A host cell transformed with a vector comprising a polynucleotide encoding a polypeptide comprising:

- a) a signal peptide comprising consisting of the sequence of SEQ ID NO: 4;
- b) a proregion comprising consisting of the sequence of SEQ ID NO:5;
- c) a mature peptide comprising consisting of the sequence SEQ ID NO: 6; or
- d) a polypeptide comprising an amino acid consisting of the sequence of SEQ ID NO: 3 at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or
- ~~————— e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6;~~

~~wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;~~

~~wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 5; and combinations thereof;~~

~~wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 6; antimicrobial activity, and cytotoxic activity;~~

~~wherein said fragment of SEQ ID NO: 4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;~~

~~wherein said fragment of SEQ ID NO: 5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5; and combinations thereof; and~~

~~wherein said fragment of SEQ ID NO: 6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6; antimicrobial activity, and cytotoxic activity.~~

90 (previously presented). The host cell according to claim 89, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

91 (previously presented). The host cell according to claim 89, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

92 (currently amended). A host cell comprising a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

a) a polypeptide comprising the sequence of SEQ ID NO: 6; and

~~b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and~~

~~————— e) b) a polypeptide comprising consisting of a fragment of SEQ ID NO: 6 comprising at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6; wherein said polynucleotide encodes a polypeptide that fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity and cytotoxic activity.~~

93 (previously presented). The host cell according to claim 92, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

94 (previously presented). The host cell according to claim 92, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

95 (currently amended). A method of producing a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

a) a polypeptide comprising the sequence of SEQ ID NO: 3; and

~~b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 3; and~~

~~————— e) b) a polypeptide comprising consisting of a fragment of at least of SEQ ID NO: 6 comprising at least 10 consecutive amino acids of SEQ ID NO: 3; wherein said polynucleotide encodes a polypeptide that fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity and cytotoxic activity.~~

96 (previously presented). The method according to claim 95, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

97 (previously presented). The method according to claim 95, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

98 (currently amended). A method of producing a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide encoding a polypeptide comprising:

- a) a signal peptide ~~comprising~~ consisting of the sequence of SEQ ID NO: 4;
- b) a proregion comprising the sequence of SEQ ID NO:5;
- c) a mature peptide comprising the sequence SEQ ID NO: 6; or
- d) a polypeptide ~~comprising an amino acid~~ consisting of the sequence of SEQ ID

NO: 3 at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or

~~_____ e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6;~~

~~_____ wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO: 4; and combinations thereof;~~

~~_____ wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO:3 or SEQ ID NO: 5; and combinations thereof;~~

~~_____ wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO:3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;~~

~~_____ wherein said fragment of SEQ ID NO:4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO: 4; and combinations thereof;~~

~~_____ wherein said fragment of SEQ ID NO:5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO: 5; and combinations thereof; and~~

~~_____ wherein said fragment of SEQ ID NO:6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO:6, antimicrobial activity, and cytotoxic activity.~~

99 (previously presented). The method according to claim 98, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

100 (previously presented). The method according to claim 98, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

101 (currently amended). A method of producing a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

a) a polypeptide comprising the sequence of SEQ ID NO: 6; and

~~b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and~~

~~_____ e) b) a polypeptide comprising consisting of a fragment of at least of SEQ ID NO: 6 of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6; wherein said polynucleotide encodes a polypeptide that fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity and cytotoxic activity.~~

102 (previously presented). The method according to claim 101, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

103 (previously presented). The method according to claim 101, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

104 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a mature peptide consisting of the sequence of SEQ ID NO: 3.

105 (new). The isolated polynucleotide according to claim 104, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

Remarks

Claims 53-103 are pending in the subject application. By this Amendment, Applicants have amended claims 53, 54, 56, 58-61, 70, 71, 75-77, 80, 83, 86, 89, 92, 95, 98, and 101, canceled claims 62-69 and 74, and added new claims 104 and 105. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 53-61, 70-73, 75-104 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants acknowledge the Examiner's indication that claims 55, 61, and 73 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims.

Applicants note that the Office Action dated May 6, 2005 indicated that no Information Disclosure Statement (IDS) appears to have been filed. Applicants provided a copy of the IDS in their Amendment dated May 5, 2004 and pointed out that an IDS for the subject application was facsimile transmitted to the Patent Office on April 1, 2002, along with a copy of the transmission report indicating that the facsimile sent to the Patent Office. However, Applicants respectfully assert that the IDS was not returned with the August 11, 2004 or the instant Action as having been considered and made of record. Accordingly, Applicants respectfully request that the Examiner consider and make of record the IDS previously submitted in the next communication from the Patent Office.

Applicants also request the electronic records of the Patent Office be updated to reflect the new title presented in the Amendment dated May 5, 2004, in accordance with the Examiner's request. A review of the Patent Office electronic records indicates the new title is not yet reflected therein.

Claims 53, 54, 56-60, 62-72, and 74-103 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had

possession of the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

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and Trademark Office on January 10, 2005.

Frank C. Eisenschenk
Frank C. Eisenschenk, Ph.D., Patent Attorney



AMENDMENT UNDER 37 C.F.R. § 1.111

Examining Group 1644

Patent Application

Docket No. GEN-100D1

Serial No. 10/045,180

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : F. Pierre VanderVegt, Ph.D.
Art Unit : 1644
Applicants : Lydie Bougueleret, Ilya Chumakov
Serial No. : 10/045,180
Filed : October 18, 2001
Conf. No. : 4857
For : Nucleic Acids and Vectors Encoding Human Defensin Polypeptide and
Applications Thereof

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

AMENDMENT UNDER 37 C.F.R. § 1.111

Sir:

A Petition and Fee for a two-month Extension of Time through and including January 11, 2005, accompanies this Amendment.

In response to the Office Action dated August 11, 2004, please amend the above-identified patent application as follows:

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In the Claims

1-52 (canceled)

53. (new). An isolated polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 3; or
- b) a polypeptide comprising a fragment of at least 10 consecutive amino acids of SEQ ID NO: 3;

wherein said isolated polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity, and cytotoxic activity.

54 (new). The isolated polynucleotide according to claim 53, wherein said polynucleotide encodes a polypeptide fragment comprising at least 15 consecutive amino acids.

55 (new). The isolated polynucleotide according to claim 53, wherein said polynucleotide encodes a polypeptide comprising the sequence of SEQ ID NO: 3.

56 (new). The isolated polynucleotide according to claim 53, wherein said polynucleotide encodes a polypeptide comprising a fragment of at least 10 consecutive amino acids of the polypeptide of SEQ ID NO: 3.

57 (new). The isolated polynucleotide according to claim 53, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

58 (new). An isolated polynucleotide encoding a polypeptide comprising:

- a) a signal peptide comprising the sequence of SEQ ID NO: 4;

- b) a proregion comprising the sequence of SEQ ID NO:5;
- c) a mature peptide comprising the sequence SEQ ID NO: 6;
- d) a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or
- e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 6;

wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;

wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 5; and combinations thereof;

wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;

wherein said fragment of SEQ ID NO: 4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;

wherein said fragment of SEQ ID NO:5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5; and combinations thereof; and

wherein said fragment of SEQ ID NO: 6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

59 (new). The isolated polynucleotide according to claim 58, wherein said polynucleotide encodes a polypeptide comprising a signal peptide comprising the sequence of SEQ ID NO: 4.

60 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a proregion comprising the sequence of SEQ ID NO:5.

61 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a mature peptide comprising the sequence of SEQ ID NO: 6.

62 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6.

63 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a fragment of at least 10 consecutive amino acids of the signal peptide comprising the sequence of SEQ ID NO: 4.

64 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a fragment of at least 10 consecutive amino acids of a proregion comprising the sequence of SEQ ID NO:5.

65 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising a fragment of at least 10 consecutive amino acids of a mature peptide comprising the sequence of SEQ ID NO: 6.

66 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide encodes a polypeptide comprising at least 15 consecutive amino acids.

67 (new). The isolated polynucleotide according to claim 62, wherein said polynucleotide encodes a polypeptide having an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4.

68 (new). The isolated polynucleotide according to claim 62, wherein said polynucleotide encodes a polypeptide having an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO:5.

69 (new). The isolated polynucleotide according to claim 62, wherein said polynucleotide encodes a polypeptide having an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 6.

70 (new). The isolated polynucleotide according to claim 54, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

71 (new). An isolated polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 6;
- b) a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and
- c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6;

wherein said isolated polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

72 (new). The isolated polynucleotide according to claim 71, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

73 (new). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide comprising the sequence of SEQ ID NO: 6.

74 (new). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 6.

75 (new). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide comprising a fragment of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6.

76 (new). The isolated polynucleotide according to claim 71, wherein said polynucleotide encodes a polypeptide comprising at least 15 consecutive amino acids.

77 (new). A vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 3;
- b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 3; and
- c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of SEQ ID NO: 3;

wherein said polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity, and cytotoxic activity.

78 (new). The vector according to claim 77, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

79 (new). The vector according to claim 77, further comprising elements ensuring the expression of said polynucleotide in a host cell.

80 (new). A vector comprising a polynucleotide encoding a polypeptide comprising:

- a) a signal peptide comprising the sequence of SEQ ID NO: 4;
- b) a proregion comprising the sequence of SEQ ID NO:5;
- c) a mature peptide comprising the sequence SEQ ID NO: 6;
- d) a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or
- e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6;

wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;

wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 5; and combinations thereof;

wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;

wherein said fragment of SEQ ID NO: 4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;

wherein said fragment of SEQ ID NO:5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5; and combinations thereof; and

wherein said fragment of SEQ ID NO: 6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

81 (new). The vector according to claim 80, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

82 (new). The vector according to claim 80, further comprising elements ensuring the expression of said polynucleotide in a host cell.

83 (new). A vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 6;
- b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and
- c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6;

wherein said polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

84 (new). The vector according to claim 83, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

85 (new). The vector according to claim 83, further comprising elements ensuring the expression of said polynucleotide in a host cell.

86 (new). A host cell transformed with a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 3;
- b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 3; and

c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of SEQ ID NO: 3;

wherein said polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity, and cytotoxic activity.

87 (new). The host cell according to claim 86, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

88 (new). The host cell according to claim 86, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

89 (new). A host cell transformed with a vector comprising a polynucleotide encoding a polypeptide comprising:

- a) a signal peptide comprising the sequence of SEQ ID NO: 4;
- b) a proregion comprising the sequence of SEQ ID NO:5;
- c) a mature peptide comprising the sequence SEQ ID NO: 6;
- d) a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or
- e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6;

wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;

wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 5; and combinations thereof;

wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;

wherein said fragment of SEQ ID NO: 4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 4; and combinations thereof;

wherein said fragment of SEQ ID NO: 5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 5; and combinations thereof; and

wherein said fragment of SEQ ID NO: 6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

90 (new). The host cell according to claim 89, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

91 (new). The host cell according to claim 89, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

92 (new). A host cell comprising a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 6;
- b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and
- c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6;

wherein said polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

93 (new). The host cell according to claim 92, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

94 (new). The host cell according to claim 92, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

95 (new). A method of producing a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 3;
- b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 3; and
- c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of SEQ ID NO: 3;

wherein said polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3, antimicrobial activity, and cytotoxic activity.

96 (new). The method according to claim 95, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

97 (new). The method according to claim 95, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

98 (new). A method of producing a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide encoding a polypeptide comprising:

- a) a signal peptide comprising the sequence of SEQ ID NO: 4;
- b) a proregion comprising the sequence of SEQ ID NO:5;
- c) a mature peptide comprising the sequence SEQ ID NO: 6;
- d) a polypeptide comprising an amino acid sequence at least 90% identical over the full length to the amino acid sequence of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6; or
- e) a fragment comprising at least 10 consecutive amino acids of SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO: 6;

wherein said signal peptide has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO: 4; and combinations thereof;

wherein said proregion has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of NO:3 or SEQ ID NO: 5; and combinations thereof;

wherein said mature peptide has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of NO:3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity;

wherein said fragment of SEQ ID NO:4 has a function selected from the group consisting of: causes intra- or extracellular secretion of a polypeptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO: 4; and combinations thereof;

wherein said fragment of SEQ ID NO:5 has a function selected from the group consisting of: inactivates the precursor form of the defensin molecule; provides a support for the acquisition of the active conformation of the mature peptide; is recognized by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO: 5; and combinations thereof; and

wherein said fragment of SEQ ID NO:6 has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO:3 or SEQ ID NO:6, antimicrobial activity, and cytotoxic activity.

99 (new). The method according to claim 98, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

100 (new). The method according to claim 98, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

101 (new). A method of producing a polypeptide comprising culturing a host cell transformed with a vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of:

- a) a polypeptide comprising the sequence of SEQ ID NO: 6;
- b) a polypeptide comprising an amino acid sequence at least 80% identical over the full length to the amino acid sequence of SEQ ID NO: 6; and
- c) a polypeptide comprising a fragment of at least 10 consecutive amino acids of the sequence of SEQ ID NO: 6;

wherein said polynucleotide encodes a polypeptide that has at least one biological activity selected from the group consisting of recognition by an antibody specific for the polypeptide of SEQ ID NO: 3 or SEQ ID NO: 6, antimicrobial activity, and cytotoxic activity.

102 (new). The method according to claim 101, wherein said polynucleotide comprises the sequence of SEQ ID NO:2 or a fragment thereof.

103 (new). The method according to claim 101, wherein said vector further comprises elements ensuring the expression of said polynucleotide in said host cell.

Remarks

Claims 1-52 are pending in the subject application. By this Amendment, Applicants have canceled claims 1-52 and added new claims 53-103. Support for the new claims can be found throughout the subject specification and in the claims as originally filed as the newly presented claims have been rewritten from those previously presented. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 53-103 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants acknowledge the Examiner's withdrawal of the objections and the rejections under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 101. Applicants also acknowledge the Examiner's indication that claims 5, 7-15, 17-19, and 41-52 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims.

Applicants note that the Office Action dated January 5, 2004 indicated that no Information Disclosure Statement (IDS) appears to have been filed. Applicants provided a copy of the IDS in their Amendment dated May 5, 2004 and pointed out that an IDS for the subject application was facsimile transmitted to the Patent Office on April 1, 2002, along with a copy of the transmission report indicating that the facsimile sent to the Patent Office. However, Applicants respectfully assert that the IDS was not returned with the instant Action as having been considered and made of record. Accordingly, Applicants respectfully request that the Examiner consider and make of record the IDS previously submitted in the next communication from the Patent Office.

Applicants also request the electronic records of the Patent Office be updated to reflect the new title presented in the last Amendment. A review of the Patent Office electronic records indicates the new title is not yet reflected therein.

Claims 1-4, 6, 16, and 20-40 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; however, in the interest of expediting prosecution in this matter, Applicants have rewritten the claims to conform to subject matter previously indicated as allowable by the Examiner. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed

invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

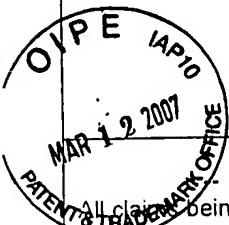
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Notice of Allowability

Application No.	Applicant(s)	
10/045,180	BOUGUELERET ET AL.	
Examiner	Art Unit	
F. Pierre VanderVegt	1644	

The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
 herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS
 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative
 of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to papers filed 3/28/2006.
2. ☒ The allowed claim(s) is/are 53-57, 61, 71-73, 75-79, 83-88, 92-97 and 101-103.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All · b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>04282006</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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Art Unit: 1644

EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment that places this application in condition for allowance. During a telephone conversation conducted on April 28, 2006, Frank C. Eisenschenk requested an extension of time for ONE (1) MONTH(S) and authorized the Director to charge Deposit Account No. 19-0065 the required fee of \$60.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

IN THE CLAIMS:

In claim 54, at the end of the claim, the recitation of --wherein said fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 56, at the end of the claim, the recitation of --wherein said fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 57, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 3 comprising at least 10 consecutive amino acids of SEQ ID NO: 3 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 72, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 6 comprising at least 10 consecutive amino acids of SEQ ID NO: 6 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 75, at the end of the claim, the recitation of --wherein said fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

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In claim 76, at the end of the claim, the recitation of --wherein said fragment has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 78, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 3 comprising at least 10 consecutive amino acids of SEQ ID NO: 3 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 84, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 6 comprising at least 10 consecutive amino acids of SEQ ID NO: 6 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 87, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 3 comprising at least 10 consecutive amino acids of SEQ ID NO: 3 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 93, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 6 comprising at least 10 consecutive amino acids of SEQ ID NO: 6 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 95, line 5, the recitation of "6" has been replaced by --3--.

In claim 96, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 3 comprising at least 10 consecutive amino acids of SEQ ID NO: 3 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

In claim 102, at the end of the claim, the recitation of --wherein said fragment encodes a polypeptide consisting of a fragment of SEQ ID NO: 6 comprising at least 10 consecutive amino acids of

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SEQ ID NO: 6 and has at least one biological activity selected from antimicrobial activity or cytotoxic activity-- has been added.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *RV*
Patent Examiner
April 28, 2006

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MAR 14 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,105,651

Page 1 of 1

APPLICATION NO.: 10/045,180

DATED : September 12, 2006

INVENTORS : Lydie Bougueleret, Ilya Chumakov

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12,

Line 22, "EDNA" should read --cDNA--.

Column 17,

Line 33, "specific allele »))" should read --specific allele »)--.

Column 41,

Line 26, "ofa" should read --of a--.

Line 34, "ofa" should read --of a--.

Column 42,

Line 45, "form" should read --from--.

Column 44,

Line 10, "consisting or" should read --consisting of--.

Line 14, "6" should read --3--.

MAILING ADDRESS OF SENDER:

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